K120288

SEP 19 2012

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

Submitter Information

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Date: August 30, 2012

Trade Name: OrthoCAD software option for G-scan

Common Name: System, Image Processing, Radiological

Classification Name(s): Picture archiving and communications system

Classification Number: LLZ

Predicate Device(s)

Trade name	Common name	Class	Product code	Manufacturer	K number
G-scan	System, nuclear magnetic resonance imaging	II	LNH	Esaote S.p.A.	K111803
SpineAnalyzer	Spine Analysis Software	II	LLZ	OPTASIA MEDICAL	K103475

Device Description

The OrthoCAD software option is a software package intended to be used with Esaote G-scan system cleared via K111803. OrthoCAD provides the morphometry of the lumbo-sacral section of the spine, by means of semi-automatic segmentation of MR images, the generation of the relative 3D model and calculation of the significant geometrical properties of the vertebral bodies and spinal canal. When this data is interpreted by a trained physician, it can yield information that may assist diagnosis.

G-scan is a Magnetic Resonance (MR) system, which produces images of the internal structures of the patient's limbs and joints.

The OrthoCAD system allows you to visualize, analyse and compare Magnetic Resonance images. The system is connected to a database that enables the physician to keep track of all the patients examined over time.

The images are acquired by running FSE T2 Rel sequences on the G-scan of the lumbo-sacral tract of the vertebral spine, in the sagittal plane, and are transferred to the OrthoCAD database following acquisition.

When the MR images are stored on the OrthoCAD database, the user can proceed with a manual or semi-automatic (wizard) segmentation of the vertebral bodies (from L1 up to S1) and of the spinal canal. During the segmentation of the anatomical elements, 3D models are constructed based on the segmented structures.

When the segmentation procedure has been terminated, the user can proceed with the evaluation of the following significant clinical parameters:

- Vertebral wedging
- Listhesis index
- Intervertebral translation index
- Intervertebral angles
- Vertebral collapse index
- Spinal curvature
- Spinal canal thickness
- Spinal canal section
- Foramen area

Following this process, the endoscopic virtual navigation within the segmented spinal canal is enabled.

Finally, if the user has worked on MR images acquired both in the clinostatic and orthostatic mode, the measures calculated and the virtual navigation of the two the positions can be compared, and a report containing all the information is produced.

OrthoCAD is made up of six environments:

- **Patient Management**: contains the functions required for the display and management of patients stored in the database associated with the system.
- **Home**: keeps track of the procedures executed overtime for the selected patient (analyses present, status of examinations associated with the various analyses, etc.).
- **Segmentation**: carries out the functions used for the segmentation and those related to the construction of 3D models of anatomic elements
- **Measurements**: includes all tools required to measure the clinical parameters used for the analysis of the currently selected exam.
- **Navigation**: enables endoscopic virtual navigation within the segmented anatomical structures by means of the definition of anatomic points, in order to construct one (or more) navigation routes.
- **Comparison**: enables the comparison of two different examinations within the same analysis or within different analyses provided they are the same type. This environment enables:
  - The simultaneous display, or superimposed display when required, of anatomical elements which belong to the two volumes being compared.
  - The simultaneous display of the different measurements, with an indication of the main differences between these values.

Intended Use(s)

OrthoCAD is an option that provides the morphometry of the lumbo-sacral section of the spine, by means of semi-automatic segmentation of MR images, the generation of the relative 3D model and calculation of the significant geometrical properties of the vertebral bodies and spinal canal. When this data is interpreted by a trained physician, it can yield information that may assist diagnosis.

Technological Characteristics

The addition of the OrthoCAD Software Option, reflected in this 510(k), does not alter the fundamental scientific technology of the G-scan system, cleared via K111803.

Performance Data

Non-clinical testing of the G-scan system with the addition of the OrthoCAD Software Option demonstrated that it met performance requirements and is as safe and effective as the predicate devices.

Tests performed:

- Comparison between the manual and semi-automated segmentation on lumbar and first sacral vertebrae
- Comparison between the manual and semi-automated segmentation on spinal canal
- Comparison of the manual and semi-automated measurements and evaluation of variability, repeatability and reproducibility
- Validation of new software OrthoCAD in its correctness in measuring MRI images f the Lumbar spine

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 19 2012

Esaote S.p.A.
% Ms. Allison Scott
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INDIANAPOLIS IN 46268

Re: K120288
Trade/Device Name: OrthoCAD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 30, 2012
Received: August 31, 2012

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

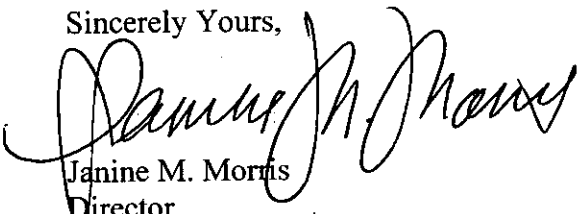
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120288

Device Name: OrthoCAD

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K120288